

### REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-42 were pending. As set forth above, Applicants have canceled claims 21, 23, and 27 without prejudice to the filing of any divisional, continuation, or, continuation-in-part application. Applicants further submit that claims 1, 4-10, 18, 21, 22, 26, 32-34, 36, and 41 have been amended to more clearly define the subject matter encompassed by the Applicants' invention, and claims 13, 15, 37, 40, and 42 have been hereby amended for mere editorial purposes to correct obvious inadvertent typographical errors. Support for claim amendments may be found in the specification as originally filed. No new matter has been added. Therefore, claims 1-20, 22, 24-26, and 28-42 are currently pending.

### **OBJECTION TO DISCLOSURE**

In the Office Action dated February 28, 2003, the Disclosure was objected to for lacking the application serial number for the U.S. Patent Application referred to at page 34, line 1 of the specification. In addition, the Patent Office has requested that the status of U.S. Patent Application referred to at page 35, line 11, be updated.

Applicants respectfully submit that the specification has been amended, as set forth above, to include U.S. Patent Application Serial Number 09/948,374 at page 34, line 1, and that the status of U.S. Patent Application Serial Number 09/760,328 has been updated at page 35, line 11 to reflect that this application has now issued as U.S. Patent No. 6,511,962. Accordingly, Applicants respectfully submit that this objection has been obviated.

### **REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

In the Office Action, claims 13, 14, 18, 21, 22, 26, 34 and 36 were rejected under 35 U.S.C. §112, second paragraph, as indefinite.

As an initial matter, Applicants wish to thank the Examiner for identifying the obvious inadvertent typographical errors and or inadvertent omissions in the claims cited for this rejection, and for his helpful suggestions. In this regard, Applicants respectfully submit that the claims have been amended as set forth above to incorporate the suggested corrections.

Accordingly, Applicants respectfully submit that claims 13, 14, 18, 21, 22, 26, 34 and 36, as amended, satisfy the definiteness requirements of 35 U.S.C. §112, second paragraph, and, therefore, request that this rejection be withdrawn.

#### **OBJECTIONS TO CLAIMS**

In the Office Action, claims 1, 2 and 4-42 were objected to for various informalities. In addition, claims 33 and 40 were objected to under 37 CFR 1.75(c) as improper dependent form for failing to further limit the subject matter of a previous claims.

As an initial matter, Applicants wish to thank the Examiner for identifying the obvious inadvertent typographical errors in the objected to claims and for his helpful suggestions. In this regard, Applicants respectfully submit that the claims have been amended as set forth above to incorporate the suggested corrections. Accordingly, Applicants submit that these objections have been obviated.

#### **REJECTIONS UNDER OBVIOUSNESS-TYPE DOUBLE PATENTING**

In the Office Action, claims 1, 3-17, 19, 22-24, 26-29 and 34-36 were rejected and provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 43-65 and 69-71 of U.S. Patent No. 6,511,962 and U.S. Patent Application No. 09/904,352, respectively. In particular, it is asserted that although the conflicting claims are not identical, they are not patentably distinct from each other.

Applicants respectfully traverse this ground of rejection. With regard to the rejection over U.S. Patent Application No. 6,511,962, Applicants submit herewith, without acquiescing to the assertion of the Office Action, a Terminal Disclaimer in which the statutory portion of the patent issuing from the instant application that exceeds the term of U.S. Patent No. 6,511,962 is disclaimed, which obviates the present rejection. With regard to the provisional rejection over co-pending U.S. Patent Application No. 09 904,352, Applicants respectfully submit that due to the provisional nature of this rejection, it can be more appropriately addressed in the co-pending application when those claims are in condition for allowance.

Accordingly, Applicants respectfully request that these grounds of rejection be withdrawn.

#### **STATEMENT OF COMMON OWNERSHIP**

The Examiner has noted that both U.S. Patent No. 6,511,962 and U.S. Patent Application No. 09/904,352, could form the basis for a rejection of claims 1, 3-17, 19, 22-24, 26-29 and 34-36 under 35 U.S.C. §103(a) if the instant application was not commonly owned at the time the invention was made.

Applicants respectfully submit that U.S. Patent No. 6,511,962 and U.S. Patent Application No. 09/904,352 were, at the time the invention of U.S. Patent Application No. 09/904,756 was made, owned by IntraBiotics Pharmaceuticals, Inc. The Assignment of U.S. Patent No. 6,511,962 to IntraBiotics Pharmaceuticals, Inc. was recorded in the U.S. Patent and Trademark Office on January 12, 2001, at Reel No. 011476 and Frame No. 0937. The Assignment of U.S. Patent Application No. 09/904,756 to IntraBiotics Pharmaceuticals, Inc. was recorded in the U.S. Patent and Trademark Office on September 5, 2001, at Reel No. 012151 and Frame No. 0226. The Assignment of U.S. Patent Application No. 09/904,352 to IntraBiotics Pharmaceuticals, Inc. was recorded in the U.S. Patent and Trademark Office on September 5, 2001, at Reel No. 012150 and Frame No. 0683. The Assignment of U.S. Patent Application No. 09/904,756 to IntraBiotics Pharmaceuticals, Inc. was recorded in the U.S. Patent and Trademark Office on September 5, 2001, at Reel No. 012151 and Frame No. 0226. Subsequently, U.S. Patent No. 6,511,962, and U.S. Patent Application Nos. 09/904,352 and 09/904,756, were acquired by Micrologix Biotech Inc. the current assignee of record.

In view of the above statement, Applicants respectfully submit that sufficient evidence has been provided to establish common ownership of the above-identified patent and patent application at the time the invention of the instant application was made.

#### **REJECTION UNDER U.S.C. §102(e)**

In the Office Action, claims 4-17, 19, 22-24, 26-29 and 34-36 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,511,962 (Borders *et al.*). In particular, it is

alleged that Borders *et al.* qualifies as prior art because claims 4-17, 19, 22-24, 26-29 and 34-36 are not deemed to be entitled under 35 U.S.C. §120 to the benefit of the filing date of the parent application 09.760,328 (*i.e.*, the application that yielded the Borders *et al.* patent).

Applicants respectfully traverse this ground of rejection and respectfully disagree with the assessment that Borders *et al.* qualifies as prior art. Nevertheless, Applicants respectfully submit, without acquiescing to the assessment of priority by the Patent Office, that the alleged lack of the benefit of the instant application to the filing date of the parent application has been rendered moot in view of the pending currently pending claims. Thus, Borders *et al.* fail to teach or suggest an antimicrobial sulfonamide derivative according to the instant invention.

Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. §102(e) be withdrawn.

#### **REJECTIONS UNDER 35 U.S.C. § 102(b)**

(1) In the Office Action, claims 1-4, 11-17, 22, 26, 30, 31 and 34-36 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 3,817,973 (Bouchaudon *et al.*). In particular, it is alleged that Bouchaudon *et al.* discloses antibiotic compounds that consist of a sulfonamide group, and a lipophilic moiety of 3-18 carbon atoms, as claimed in the instant invention.

Applicants respectfully traverse this ground of rejection and submit that Bouchaudon *et al.* fail to meet every limitation of the instant claims and, therefore, fail to anticipate the claimed invention. As disclosed in the specification and recited in the claims, the present invention is directed, in part for this rejection, to an antimicrobial sulfonamide derivative, or a salt or a hydrate thereof, comprising a core cyclic peptide or core antibiotic of a lipopeptide antibiotic; and a lipophilic moiety, wherein said lipophilic moiety is covalently attached to the core cyclic peptide or core antibiotic *via* a linking chain which includes a sulfonamide linkage and wherein said core cyclic peptide or core antibiotic is not of laspartomycin or polymyxin. Bouchaudon *et al.* fail to teach or suggest how to make or use anything other than polymyxin derivatives. Thus, Bouchaudon *et al.* fail to provide every element of the instant claims.

Accordingly, Applicants respectfully submit that the instant claims distinguish patentably over Bouchaudon *et al.* and, therefore, satisfy the requirement of 35 U.S.C. §102(b). Applicants request that this rejection be withdrawn.

(2) In the Office Action, claims 1-4, 12, 30, 31, 34-38 and 40-42 have been rejected under 35 U.S.C. §102(b) as anticipated by WO 98/00173 (Zhao *et al.*). In particular, it is alleged that Zhao *et al.* discloses a drug that can be an antibiotic conjugated through a sulfonamide group to an optionally substituted phenyl, or 5- or 6-membered heterocyclic ring, which can be reacted with the appropriate sulfonyl chloride to form the final conjugated product, as claimed in the instant invention.

Applicants respectfully traverse this ground of rejection and submit that Zhao *et al.* fail to meet every limitation of the instant claims and, therefore, fail to anticipate the claimed invention. Zhao *et al.* merely describe the use of glutathione S-transferase (GST) for adding specific moieties to drugs via a sulfonamide bond to create prodrugs. Although Zhao *et al.* provide a laundry list of compounds that can be modified using GST, none of the compounds disclosed are lipopeptide antibiotics. The closest compound is actinomycin, but this compound is not a lipopeptide and it is not an antibiotic (*i.e.*, it is a chemotherapeutic agent). Therefore, Zhao *et al.* fail to provide every element of the instant claims.

Accordingly, Applicants respectfully submit that the present invention satisfies the requirements of 35 U.S.C. § 102(b) and, therefore, request that this rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims pending in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.



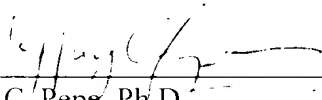
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PATENT TRADEMARK OFFICE

Respectfully submitted,

William V. Curran *et al.*

Seed Intellectual Property Law Group PLLC

  
Jeffrey C. Pepe, Ph.D.

Registration No. 46,985

(JCP Imp) 375446

Enclosure:

Terminal Disclaimer (U.S. Patent No. 6,511,962)

Phone: (206) 622-4900

Fax: (206) 682-6031